UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORKX	DOC #
BETTY SUNDHAUSEN AND JES SUNDHAUSEN,	CASE NUMBER:
Plaintiff,	
-against-	COMPLAINT AND DEMAND <u>FOR JURY TRIAL</u>
PFIZER, INC.,	
Defendant.	
X	

Plaintiffs, by their attorneys, DOUGLAS & LONDON, P.C., upon information and belief, at all times hereinafter mentioned, allege as follows:

#### **JURISDICTION**

This Court has jurisdiction pursuant to 28 United States Section 1332, in that... 1. Plaintiff is a citizen of a State, which is different from the State where Defendant is incorporated and has their principal places of business. The amount in controversy exceeds SEVENTY-FIVE THOUSAND DOLLARS (\$75,000.00) as to the Plaintiff.

#### NATURE OF THE CASE

2. Defendant, PFIZER, INC. (hereinafter referred to as "PFIZER"), designed, tested, researched, manufactured, marketed, advertised, sold and distributed Bextra, for the treatment of arthritis and acute pain.

- As a result of the defective nature of Bextra, Plaintiff herein, has suffered severe 3. and permanent personal injuries, other severe and permanent health consequences that are lasting in nature including but not limited to heart attacks, strokes, blood clots, kidney damage, as well as other severe and permanent health consequences.
- 4. Defendant, PFIZER, concealed its knowledge of Bextra's defects, hazards, and test results from the Plaintiffs and their physicians and pharmacists.
- 5. Defendant, PFIZER, failed to adequately conduct testing and/or research on Bextra, prior to marketing, manufacturing, distributing, and/or selling said drug.
- 6. Defendant, PFIZER, failed to adequately conduct post-marketing surveillance and/or testing of its drug Bextra subsequent to its marketing, manufacturing, distribution, and/or selling of said drug.
- 7. Defendant under-reported, underestimated and downplayed the serious and dangerous side effects of Bextra.

### PARTY PLAINTIFF

- 8. Plaintiff, BETTY SUNDHAUSEN, is and at all times hereto was a resident of St. Louis, Missouri.
- 9. Plaintiff, BETTY SUNDHAUSEN, was prescribed and began taking Bextra in or about March 2002 and consistently ingested Bextra until in or about May 2004. At all times mentioned, Plaintiff, BETTY SUNDHAUSEN, used Bextra as prescribed and in a foreseeable manner.

- 10. As a direct and proximate result of ingesting Bextra, Plaintiff,
- BETTY SUNDHAUSEN, suffered cardiac distress and underwent stint placement, experienced severe pain and suffering, and has sustained permanent injuries and emotional distress.
- 11. Defendant, PFIZER is incorporated in the State of Delaware, with its principal place of business at 235 East 42<sup>nd</sup> Street, New York, New York 10017.
- 12. Defendant, PFIZER, was and still is a domestic corporation that is doing business in the State of New York.
- 13. Defendant, PFIZER, transacts and conducts business in the State of New York.
- 14. Defendant, PFIZER, regularly does and/or solicits business within the State of New York.
- 15. Defendant, PFIZER, derives substantial revenue from goods used or consumed in the State of New York.
- 16 Defendant, PFIZER, expected or should have expected its acts to have consequences within the State of New York, and derives substantial revenue from interstate commerce within the United States of America, and New York State, more particularly.
- 17. At all times relevant hereto, Defendant PFIZER was engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling and/or marketing, either directly or indirectly through third parties or related entities, the drug, Bextra, throughout the United States.

18. This Court has personal jurisdiction over PFIZER as the company is present, domiciled and/or doing business within New York. Upon information and belief, PFIZER is licensed to do business in New York, transacts business in New York, and a substantial part of the events and/or omissions giving rise to the claims occurred in New York.

#### FACTUAL BACKGROUND

- 19. The Food and Drug Administration (hereinafter referred to as "the FDA") first approved Bextra in November 2001 for the treatment of osteoarthritis, rheumatoid arthritis and primary dysmenorrhea.
- Bextra is the brand name of valdecoxib, one of a class of drugs called non-20. steroidal anti-inflammatory drugs ("NSAIDs") which work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, arthritis and muscle pain, among other conditions.
- 21. Bextra is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites, and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.
- Despite having clinical data in its possession confirming an increased risk of 22. cardiovascular injury, Defendant, PFIZER represented to consumers, their physicians, and/or Plaintiffs that Bextra was safe, and that any cardiovascular and/or cardiothrombotic side effects were not associated with the drug.

- 23. On October 15, 2004, PFIZER announced that studies did in fact demonstrate that the occurrence of strokes and heart attacks among Bextra users was more that double that of individuals given placebos.
- 24. On April 7, 2005 the FDA ordered PFIZER to issue a Bextra recall due to significant concerns about the safety of their top-selling painkiller.
- 25. Defendant, either directly or through its agents, servants, and employees, designed, manufactured, marketed, advertised, distributed, and sold Bextra for the treatment of arthritis and acute pain.
- 26. Defendant did not warn consumers in any way and/or adequately warn, including Plaintiff, about the risk of cardiovascular, strokes, heart attacks, kidney damages, and/or other serious injuries caused by Bextra.
- 27. Defendant misrepresented and failed to appropriately warn consumers, including Plaintiffs, and the medical community of the dangerous risk of suffering a stroke or heart attack, as well as other severe and permanent health consequences caused by Bextra, and consequently placed its profits above the safety of its customers.
- 28. Defendant concealed its knowledge of Bextra's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.
- 29. As a result of the defective nature of Bextra, those persons who were prescribed and ingested Bextra, including Plaintiffs, have suffered and may continue to suffer severe and permanent personal injuries, including an increased risk of heart attack and stroke, as well as other severe and permanent injuries.

# FIRST CAUSE OF ACTION AS AGAINST DEFENDANT, PFIZER (NEGLIGENCE & NEGLIGENCE PER SE)

- 30. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 31. Defendant had a duty to exercise reasonable care in the warning of, designing, researching, testing, labeling, manufacturing, marketing, supplying, promoting, packaging, selling, and/or distribution of Bextra, including a duty to ensure that Bextra did not cause users to suffer from unreasonable, unknown, and/or dangerous side effects.
- 32. Defendant failed to exercise reasonable care in the warning about, designing, researching, testing, labeling, manufacturing, marketing, supplying, promoting, packaging, selling, and/or distribution of Bextra into interstate commerce in that Defendant knew or should have known that taking Bextra caused unreasonable and dangerous injuries, including stroke, heart attack, and death.
- 33. Defendant breached its duty and was negligent in its actions, is representations, and omissions toward Plaintiff, in part, in the following ways:
  - Failed to exercise due care in designing, testing, developing, and manufacturing Bextra so as to avoid the aforementioned risks to individuals, including but not limited to Plaintiff herein, who were using Bextra;
  - b. Failed to include adequate warnings with Bextra that would alert Plaintiffs and other consumers, and/or their prescribing physicians to its potential risks and serious side effects:

- Failed to adequately and/or properly test Bextra before placing it on the c. market:
- d. Failed to conduct sufficient testing and/or tests of/on Bextra, which if properly performed, would have shown that Bextra had serious side effects, including, but not limited to, stroke, heart attack, and death;
- Failed to adequately warn Plaintiff and/or his/her/their physician(s) that e. use of Bextra carried a risk of disability and death due to stroke, heart attack, and other serious side effects;
- f. Failed to provide adequate post-marketing warnings or instructions after Defendant knew, or should have known, of the significant risks of stroke, heart attack, and death from the use of Bextra;
- Failed to warn Plaintiffs prior to actively encouraging the sale of Bextra, g. either directly or indirectly, orally or in writing, about the need for comprehensive, regular medical monitoring to ensure early discovery of potentially serious side effects;
- h. Placed an unsafe product into the stream of commerce; and
- i. Were otherwise careless and/or negligent.
- 34. Defendants under-reported, underestimated and/or downplayed the serious and dangerous side effects of Bextra.
- 35. Defendant knew, or should have known, that Bextra caused unreasonably dangerous risks and serious side effects of which individuals, including but not limited to Plaintiff herein, and/or their physicians would not be aware.
- 36. Defendant knew or should have known that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise reasonable care as described herein.
- 37. Despite the fact that Defendant, PFIZER, knew or should have known that Bextra caused unreasonably dangerous side effects, Defendant continued to market,

manufacture, distribute and/or sell Bextra to consumers, including but not limited to Plaintiffs herein, until April 7, 2005, when the FDA forced Defendant, PFIZER, to withdraw Bextra from the market.

- 38. Defendant, PFIZER, knew or should have known that consumers, such as Plaintiffs herein, would foreseeably suffer injury as a result of Defendant, PFIZER's failure to exercise ordinary care.
- As a direct and proximate result of Defendant's negligence as described herein, 39. Plaintiffs have sustained harm, including permanent and debilitating injuries. These injuries have caused, and will continue to cause, extensive pain and suffering and severe emotional distress, and have substantially reduced Plaintiffs' ability to enjoy life and loss of earnings; and have caused, and will continue to cause, Plaintiffs to expend substantial sums of money for medical, hospital, and related care, all to Plaintiffs' general damage.
- 40. As a result of the foregoing acts and omissions, the Plaintiffs herein were, and/or still are, caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses, and other serious injuries, which are permanent and lasting in nature.
- 41. As a direct and proximate result of Defendant's negligence as described herein, Plaintiff has incurred expenses for reasonable and necessary healthcare treatment and services. Upon information and belief, Plaintiffs will be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

42. By reason of the foregoing, Plaintiffs have been damaged as against the defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

### SECOND CAUSE OF ACTION AS AGAINST DEFENDANT, PFIZER (STRICT PRODUCTS LIABILITY)

- 43. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- At all times herein mentioned, the Defendant, PFIZER, manufactured, 44. compounded, distributed, recommended, supplied, merchandized, advertised, promoted and/or sold, the aforesaid Bextra as hereinabove described, and Plaintiff used said product.
- That Bextra was expected to and did reach the usual consumers, handlers, and 45. persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant, PFIZER.
- At those times, the drug product Bextra, was in an unsafe, defective, and 46. inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.
- The Bextra manufactured and/or supplied by Defendant, PFIZER, was defective 47. in design or formulation in that, when it left the hands of the manufacturer and/or

suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

- 48. The Bextra manufactured and/or supplied by Defendant, PFIZER, was defective in design and/or formulation, in that, when it left the hands of the Defendant manufacturer and/or supplier, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer, including Plaintiff herein, would expect.
- 49. At all times herein mentioned, the said drug product Bextra was in a defective condition and unsafe, and Defendant, Pfizer, knew or had reason to know that said product was defective and unsafe, especially when used in the form and/or manner as provided by the Defendant, PFIZER.
- 50. Defendant, PFIZER, knew, or should have known that at all times herein mentioned its Bextra was in a defective condition, inherently dangerous and unsafe.
- 51. At the time of the Plaintiff's use of Bextra, said drug was being used for the purposes and in a manner normally intended, recommended, promoted and/or marketed by Defendant, PFIZER.
- 52. Defendant, PFIZER, with this knowledge voluntarily designed its Bextra in a dangerous condition for consumption by the public, and in particular the Plaintiff herein.
- 53. Defendant, PFIZER, had a duty to create and/or sell a product that was not unreasonably dangerous for its normal, intended use.
- 54. Defendant, PFIZER, created and/or sold a product unreasonably dangerous for its normal, intended use.

- 55. Defendant, PFIZER, designed, manufactured, and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff herein, and Defendant, Pfizer, is therefore strictly liable for the injuries sustained by the Plaintiff herein.
- 56. The Plaintiff herein could not by the exercise of reasonable care, have discovered the defects herein mentioned and/or perceived their danger.
- 57. The Bextra manufactured and/or supplied by Defendant, PFIZER, was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a high risk of developing serious injuries, including but not limited to heart attack, stroke, kidney damage, blood clots, and/or death, as well as other severe and permanent health consequences, and the Defendant, PFIZER, failed to adequately warn of said risks.
- 58. The Bextra manufactured and/or supplied by Defendant, Pfizer, was defective due to inadequate warnings and/or inadequate testing.
- 59. The Bextra manufactured and/or supplied by Defendant, Pfizer, was defective due inadequate post-marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the risks of this medication, it failed to provide adequate warnings to users, consumers, and/or prescribing physicians and pharmacies of the product, and Plaintiff in particular, and continued to promote the product.

- 60. By reason of the foregoing, the Defendant, PFIZER, has become strictly liable in tort to the Plaintiff herein for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Bextra.
- 61. Defendant, PFIZER's defective design, manufacturing defect, and inadequate warnings of Bextra were acts that amount to willful, wanton, and/or reckless conduct by Defendant, PFIZER.
- 62. That said defects in Defendant, PFIZER's Bextra were a substantial factor in causing Plaintiff's injury.
- 63. As a result of the foregoing acts and omissions, the Plaintiff herein was caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses, and other serious injuries.
- 64. As a direct and proximate result of Defendant's conduct alleged described herein, Plaintiffs have incurred expenses for reasonable and necessary healthcare treatment and services.
- 65. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

### THIRD CAUSE OF ACTION AS AGAINST DEFENDANT, PFIZER (BREACH OF EXPRESS WARRANTY)

- 66. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 67. Defendant, PFIZER, expressly warranted that Bextra was safe and well accepted by users.
- 68. Bextra does not conform to these express representations because Bextra is not safe and has numerous serious side effects.
- 69. As a direct and proximate result of the breach of said warranties, Plaintiff herein suffered severe and permanent personal injuries, harm and economic loss ultimately resulting in her death.
- 70. Plaintiff herein did rely on the express warranties of Defendant, PFIZER.
- 71. Members of the medical community, including physicians, pharmacists, and/or other healthcare professionals, relied upon the representations and warranties of the Defendant, PFIZER, for use of said drug Bextra in prescribing, recommending and/or dispensing the product.
- 72. The Defendant, Pfizer, herein breached the aforesaid express warranties, as its product Bextra was defective, as is, and has been, set forth herein.
- Defendant, PFIZER, expressly represented to the users and their physicians, 73. pharmacists, and/or other healthcare providers that said drug Bextra was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce

any dangerous side effects, and/or that it was adequately tested and fit for its intended use.

- 74. Defendant, PFIZER knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that said drug Bextra was not safe and fit for the use intended, and, in fact, produced serious injuries to the user.
- 75. That said breach(es) of warranty(ies) by Defendant, PFIZER was a substantial factor in causing Plaintiff's death.
- 76. As a result of the foregoing acts and omissions, the Plaintiff herein was caused to suffer severe personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses, and other serious injuries, which ultimately resulted in her death.
- 77. As a direct and proximate result of Defendant's conduct alleged described herein, Plaintiffs have incurred expenses for reasonable and necessary healthcare treatment and services.
- 78. By reason of the foregoing, Plaintiffs have been damaged as against each defendant

in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

# FOURTH CAUSE OF ACTION (BREACH OF IMPLIED WARRANTIES)

- 79. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 80. At all times herein mentioned, the Defendant, PFIZER, manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and/or sold Bextra.
- 81. At the time Defendant, PFIZER, marketed, sold, and distributed Bextra for use by Plaintiff herein, Defendant, Pfizer, knew of the use for which Bextra was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
- 82. The Defendant, PFIZER, impliedly represented and warranted to the users and their physicians, pharmacists, and/or healthcare providers that Bextra was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.
- 83. That said representations and warranties aforementioned were false, misleading, and/or inaccurate in that said drug product Bextra, was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.
- 84. Plaintiffs herein and/or members of the medical community did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

- 85. Plaintiffs and his/her/their physicians, pharmacists, and/or other healthcare providers reasonably relied upon the skill and judgment of Defendant, PFIZER as to whether Bextra was of merchantable quality and safe and fit for its intended use.
- 86. Bextra was injected into the stream of commerce by the Defendant, PFIZER, in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.
- 87. The Defendant, PFIZER, herein breached the aforesaid implied warranties, as its product Bextra was not fit for its intended purpose and use.
- 88. That said breach(es) of warranty(ies) by Defendant, PFIZER's was a substantial factor in causing Plaintiffs' injuries.
- 89. As a result of the foregoing acts and omissions, the Plaintiffs herein were caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses, and other serious injuries, ultimately resulting in her death.
- 90. As a direct and proximate result of Defendant's conduct alleged described herein,
  Plaintiff had incurred expenses for reasonable and necessary healthcare treatment and
  services.
- 91. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

# FIFTH CAUSE OF ACTION AS AGAINST DEFENDANT, PFIZER (FRAUDULENT MISREPRESENTATION)

- 92. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 93. The Defendant, PFIZER, falsely and fraudulently represented to the medical community, and to the Plaintiff and the public in general, that said product Bextra had been tested and found to be safe and effective for the treatment of, *inter alia*, arthritis and acute pain.
- 94. The representations made by Defendant, PFIZER, were, in fact, false, and when said representations were made, Defendant, PFIZER, knew those representations to be false and willfully, wantonly and recklessly disregarded whether the representations were true.
- 95. These representations were made by said Defendant, Pfizer, with the intent of defrauding and deceiving the Plaintiffs herein, the public in general, and/or the medical community in particular, and with the intent of inducing the Plaintiff herein, the public in general, and/or the medical community in particular, to recommend, dispense and purchase said product Bextra for use in treating arthritis and acute pain, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety and welfare of the Plaintiff herein.

- 96. At the time the aforesaid representations were made by the Defendant, PFIZER, and, at the time that Plaintiff herein used Bextra, Plaintiff wase unaware of the falsity of said representations and reasonably believed them to be true.
- 97. In reliance upon said representations, Plaintiff herein, were induced to and did use Bextra, thereby sustaining severe and permanent personal injuries, and being at an increased risk of sustaining additional and further severe and permanent personal injuries in the future.
- 98. Defendant, PFIZER, knew and was aware or should have known that Bextra had not been sufficiently tested, was defective in nature, and that it lacked adequate warnings.
- 99. Defendant, Pfizer, knew or should have known that Bextra had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous.
- 100. Defendant, PFIZER, brought Bextra to the market, and acted fraudulently, wantonly, and maliciously to the detriment of the Plaintiff herein, and others.
- 101. As a result of the foregoing acts and omissions, the Plaintiff herein was caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses ultimately resulting in her death.
- 102. As a direct and proximate result of Defendant's conduct alleged described herein, Plaintiff has incurred expenses for reasonable and necessary healthcare treatment and services.

103. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

### SIXTH CAUSE OF ACTION AS AGAINST DEFENDANT, PFIZER (FRAUDULENT CONCEALMENT)

- 104. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 105. At all times during the course of dealing between Defendant, PFIZER and Plaintiff herein, Defendant, PFIZER, misrepresented that Bextra was safe for its intended use.
- 106. Defendant, PFIZER, knew or was reckless in not knowing that its representations were false.
- 107. In representations to Plaintiff and her physicians, pharmacists, and/or other healthcare providers, Defendant, PFIZER fraudulently concealed and intentionally omitted the following material information:
- (a) that Bextra was not safe for use in treating, <u>inter alia</u>, arthritis and acute pain;
- (b) that Defendant was aware of Bextra's dangers;
- (c) That Bextra was defective, and that it caused dangerous side effects, including but not limited to heart attack, stroke, as well as other severe and permanent health consequences; and
- (d) That patients needed to be regularly monitored while taking Bextra;

- 108. Defendant, PFIZER was under a duty to disclose to Plaintiff herein and her physicians, pharmacists and/or other healthcare providers the defective nature of Bextra, and/or the risks and dangers associated with Bextra.
- 109. Defendant, PFIZER, had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence caused damage to persons who used Bextra, including the Plaintiff herein.
- 110. Defendant, PFIZER's concealment and omissions of material facts concerning, inter alia, the safety of Bextra, were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and/or her physicians, pharmacists, and/or other healthcare providers into reliance, continued use of Bextra, and actions thereon, and to cause them to purchase Bextra and/or use the product.
- 111. Defendant, PFIZER, knew that Plaintiffs and their physicians, pharmacists, and other healthcare providers had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding Bextra.
- 112. Plaintiffs herein, as well as their doctors, pharmacists, and other healthcare providers, reasonably and justifiably relied on Defendant, Pfizer's concealment and/or omissions of fact.
- 113. As a result of the foregoing acts and omissions, the Plaintiffs herein were caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses, and other serious injuries.

- 114. As a direct and proximate result of Defendant's conduct alleged described herein,
  Plaintiffs have incurred expenses for reasonable and necessary healthcare treatment and
  services.
- 115. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

# SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANT (NEGLIGENT MISREPRESENTATION)

- 116. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 117. Defendant, PFIZER, had a duty to represent and/or accurately represent to the medical and/or healthcare community, and to the Plaintiff, her physicians and pharmacists, the FDA and/or the public in general that said product, Bextra, had been tested and found to be safe and effective for pain relief medication.
- 118. The representations made by Defendant were, in fact, false.
- 119. Defendants failed to exercise ordinary care in the representation of Bextra, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendant negligently misrepresented Bextra's high risk of unreasonable, dangerous side effects.

- 120. Defendant breached their duty in representing Bextra's serious side effects to the medical and healthcare community, to the Plaintiff, her physicians and pharmacists, the FDA and the public in general.
- 121. As a result of the negligent misrepresentations of the Defendant set forth hereinabove, said Defendant knew and were aware or should have known that Bextra had been insufficiently tested, that it had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including but not limited to heart attack and stroke, as well as other severe and health consequences, including death.
- 122. As a result of the foregoing acts and omissions, the Plaintiff herein was, caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses, and other serious injuries.
- 123. As a direct and proximate result of Defendant's conduct alleged described herein, Plaintiffs have incurred expenses for reasonable and necessary healthcare treatment and services.
- 124. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

# EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANT (FRAUD AND DECEIT)

- 125. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 126. Defendant conducted research and used Bextra as part of their research.
- 127. As a result of Defendant's research and testing, or lack thereof, Defendant distributed blatantly and intentionally false information, including but not limited to assuring the public, the Plaintiffs, his/her their doctors, hospitals, healthcare professionals, and/or the FDA that Bextra was safe for use as a means of relieving arthritis and acute pain.
- 128. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, healthcare professionals, the FDA, and/or the Plaintiff, in particular.
- 129. Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff herein, as well as their respective healthcare providers and/or the FDA.
- 130. The information distributed to the public, in general, the FDA, and/or the Plaintiff by Defendant, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

- 131. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Bextra was safe for use to relieve arthritis and pain.
- 132. The information distributed to the public, in general, the FDA, and/or the Plaintiff by Defendant intentionally included false representations that Bextra was not injurious to the health and/or safety of its intended users.
- 133. These representations were false and misleading.
- 134. Upon information and belief, Defendant intentionally suppressed, ignored and disregarded test results not favorable to the Defendant's product, Bextra, and results that demonstrated that the Bextra was not safe, causing risks of heart attack, stroke, kidney damage, blood clots, other serious and permanent injuries and death.
- 135. Defendant intentionally made material representations to the FDA and the public, in general, including the medical profession, and/or the Plaintiff, regarding the safety of Bextra, specifically but not limited to Bextra not having dangerous and serious health and/or safety concerns.
- 136. Defendant intentionally made material representations to the FDA and the public, in general, including the medical profession, and/or the Plaintiff, regarding the safety of Bextra, specifically but not limited to Bextra being as safe a mean to relieve arthritis and other acute pain.
- 137. That it was the purpose of Defendant in making these representations to deceive and defraud the public, the FDA and/or the Plaintiff, to gain the confidence of the public, in general, healthcare professionals, the FDA, and/or the Plaintiffs, to falsely ensure the

quality and fitness for use of Bextra and induce the public, including but not limited to the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Bextra.

- Defendant made the aforementioned false claims and false representations with 138. the intent of convincing the public, in general, healthcare professionals, the FDA, and/or the Plaintiff that Bextra was fit and safe for use as pain reliever.
- Defendant made the aforementioned false claims and false representations with 139. the intent of convincing the public, in general, healthcare professionals, the FDA, and/or the Plaintiff that Bextra was fit and safe for use as pain relief medication.
- 140. That Defendant made claims and representations in its documents submitted to the FDA, to the public, in general, to healthcare professionals, and/or the Plaintiff that Bextra did not present a health and/or safety risk.
- That these representations and others made Defendant were false when made, 141. and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.
- 142. That these representations and others, made by Defendant, were made with the intention of deceiving and defrauding the Plaintiff herein, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Bextra.

- 143. That Defendant, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Bextra to the public at large, and/or the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not safe.
- 144. That Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Bextra by concealing the suppressing material facts regarding the dangerous and serious health and/or safety concerns of Bextra.
- 145. That Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as her as their respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Bextra and/or that her respective healthcare providers would dispense, prescribe, and/or recommend same.
- 146. Defendant, through their public relations efforts, which included but were not limited to the public statements and/or press releases, knew or should have known that the public, including the Plaintiffs, as well as their respective healthcare professionals would rely upon the information being disseminated.
- 147. Defendant utilized direct to consumer adverting to market, promote, and/or advertise Bextra.

- 148. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Bextra.
- That the Plaintiff did not discover the true facts with respect to the dangerous and 149. serious health and/or safety concerns, and the false representations of Defendant, nor could the Plaintiff with reasonable diligence have discovered the true facts.
- 150. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Bextra, Plaintiff and/or her healthcare providers would not have purchased, used and/or relied on Bextra for pain relief.
- That the Defendant's aforementioned conduct constitutes fraud and deceit, and 151. was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.
- As a result of the foregoing acts and omissions, the Plaintiffs herein were, and/or still are, caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, loss of earnings, medical expenses, and other serious injuries, which are permanent and lasting in nature.
- 153. As a direct and proximate result of Defendant's conduct alleged described herein, Plaintiffs have incurred expenses for reasonable and necessary healthcare treatment and services. Upon information and belief, Plaintiff will be required to obtain medical and/or hospital care, attention, and services in an amount as yet unascertained.

154. By reason of the foregoing, Plaintiffs have each been damaged as against each defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00) in compensatory damages and TEN MILLION DOLLARS (\$10,000,000.00) in punitive damages.

### NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (LOSS OF CONSORTIUM)

- 155. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 156. Plaintiff, JES SUNDHAUSEN, is lawfully married to Plaintiff, BETTY SUNDHAUSEN, and as such is entitled to the services, society and companionship of his spouse, the Plaintiff.
- 157. That as a result of the foregoing, Plaintiff, JES SUNDHAUSEN, was caused to sustain the loss of services, income, society, consortium and companionship of his spouse during his time of injury caused by Defendants' BEXTRA, and was caused to incur medical expenses on behalf of his spouse.
- 158. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendant on each of the abovereferenced claims and Causes of Action as set forth and requested above, and as follows:

- 1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs (past), together with interest and costs as provided by law;
- 2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;
- 3. Awarding Plaintiff reasonable attorneys fees;
- 4. Awarding Plaintiff the costs of these proceedings; and
- 5. Such other and further relief as this Court deems just and proper.

Dated: New York, New York April 3, 2008

DOUGLAS & LONDON, P. C

By:

MICHAEL A. LONDON (ML-7510)

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## **DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand trial by jury as to all issues.

MICHAEL A. LONDON (ML-7510)